



Certificate of Quality

Product Name: Growth Promotion QC SET/5
Lot Number: 042061

Product Number: R4721000
Expiration Date: 2012-04-30
(YYYY-MM-DD)

This product has been manufactured, processed and packaged in accordance with Quality Systems Regulation, 21 CFR Part 820. Representative samples were tested per Remel Quality Control specifications and were found to meet performance criteria for this product.

Purity:

Standardized aliquots of the rehydrated product are inoculated onto nonselective media and examined for pure growth following the appropriate incubation. Selective and Differential media are also tested where applicable.

Viability And Quantification:

Each organism is recovered from the preserved state within the required time frame and at an acceptable level. Passage number is stated as the current preserved state.

Macroscopic And Microscopic Morphology:

Colony morphology is consistent with documented referenced description. Traditional staining is performed.

Biochemical Analysis:

Organism exhibits characteristic biochemical and/or enzymatic reactions. Automated and/or conventional testing was performed and results were within established limits. Antimicrobial testing performed where applicable. Results within expected ranges.

		Gram Reaction:	Profile:
Candida albicans	10231	Gram Positive Yeast	Vitek YBC
Pseudomonas aeruginosa	9027	Gram Negative Rod	Vitek GNI+
Aspergillus brasiliensis	16404	N/A - Micro/Macroscopic evaluation performed	
Bacillus subtilis	6633	Gram Positive Rod	Vitek BAC
Clostridium sporogenes	11437	Gram Positive Rod	Remel RapID ANA

CFU/cap: <100 / 0.1ml

Passage: Kit - All < 5

Appearance: Preserved Gel Matrix suspended in vial cap

pH: N/A

Colony Count: Not less than 5 samples each were plated to the following:

Trypticase Soy Agar, spread plates, incubated at 35°C for 24 hours.

A. brasiliensis was plated to Potato Dextrose Agar, spread plates, incubated at 30°C for 48 hours.

C. sporogenes was plated to CDC Anaerobic Blood Agar, spread plates, incubated at 35°C, -O2, for 48 hours.

Colony forming units as noted above are specified under defined growing conditions. Results may vary with more inhibitory or selective media or with the same medium of inferior quality.

Signed

Quality Control Supervisor